UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,959	10/24/2003	Ratan K. Chaudhuri	EMI-55	6979

23599 7590 01/11/2005

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
LEITH, PATRICIA A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/691,959	CHAUDHURI, RATAN K.	
	Examiner	Art Unit	
	Patricia Leith	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *2-8,18-21,26 and 27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9-17 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 9-17 and 22-25 in the reply filed on 11/08/04 is acknowledged. The traversal is on the ground(s) that Groups I and II "are linked such that it would not be an undue burden to examine the methods of Group I and the products of Group II. The link is clear in that each of the product claims ....are dependent on claim 1 which is an independent method claim of Group I...In searching the methods for preventing photo damage to the skin...it should not be an undue burden to extend the search to dosage forms for oral administration". This is not found persuasive because as indicated in the original requirement for restriction, the search for the method will not necessarily produce the composition because it is evidenced by the claims themselves that the particulars of the composition of Group II are not present in the method claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-8, 18-21 and 26-27 were withdrawn from the merits as they are directed toward a non-elected invention.

Claims 1, 9-17 and 22-25 were examined on the merits.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the Instant case, Applicant has listed cases, but has not specifically stated how this application relates to the listed applications.

The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, **the specific reference must be submitted during the**

pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

It is noted that in order for the applications to be related, they must be co-pending. Because the priority claim is not clear on the record, the Instant application is not, at this time, afforded benefit of priority under 35 USC 120.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10, 14-17 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal (US 6,290,996 B1).

Ghosal (US 6,290,996 B1) disclosed administration of 50-500 mg per day of an aqueous or alcoholic-water salt extract of *Emblica officinalis* fruit to patients for inhibition of blood platelet aggregation (col.2, lines 17-27 and col. 4 lines 19-25). Ghosal specifically taught that the extract included Emblicanin-A and B as well as Punigluconic acid and pedunculagin (col. 2, lines 29-39). Ghosal further proposed that the composition be administered in the forms of a tablet, capsule syrup, elixir and gel (col.4, lines 19-25).

It is noted that although Ghosal did not specifically teach the embodiments of claims 15-16, that these embodiments are deemed to be an inherent property of the extract disclosed by Ghosal since the extract disclosed by Ghosal, and the extract disclosed by Applicant are the same extract (each respective extract is extracted from the same material by the same extraction method).

Further, claim 25 states 'standardized' extract. The term 'standardized' is given it's broadest interpretation within reason since the term is not given a definition in the Instant specification. It is known in the art that 'standardized' extracts are extracts in which a particular protocol is used to extract a plant material which results in an extract with predictable amounts/percentages of phytochemical constituents. The recitation of 'standardized' without disclosure of what is actually standardized; i.e., a particular flavonoid for example, is arbitrary and can be drawn to any known extract. Because the extract disclosed by Ghosal possessed particular ratios of phytochemicals, the extract is considered 'standardized' and therefore anticipates claim 25.

It is finally noted that the term 'prevent' in claim 1 is deemed to mean that administration of the product will necessarily perform the method if administered prior to sun exposure. Because the claims merely state 'administration' without any other steps, it is deemed that administration of the composition disclosed by Ghosal would have performed the effect of 'preventing' photo-damage since the same composition was administered especially absent evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9-17 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (US 6,290,996 B1) in view of Dewhirst (US 4,563,526).

The teachings of Ghosal were discussed *supra*. Ghosal did not specifically teach wherein the composition was administered in the protocols suggested by the claims; i.e., claims 11-13 and 22-24.

Dewhirst (US 4,563,526) disclosed that compounds which inhibit platelet aggregation are useful as topical antiinflammatory agents (col.1, lines 32-39).

One of ordinary skill in the art would have been motivated to topically apply the composition disclosed by Ghosal in order to treat a topically located area of inflammation. One of ordinary skill in the art would have had a reasonable expectation that because the extract of *E.officinalis* was demonstrated to possess anti-platelet aggregation, that the extract would have had a beneficial effect systemically (as shown in Ghosal) or topically (as suggested by Dewhirst).

One of ordinary skill in the art would have been motivated to apply sun screen while topically applying the composition disclosed by Ghosal while exposed to the sun in order to block harmful UV rays on the skin. The combination of elements is not mutually exclusive, and the ordinary artisan would recognize the advantage of each element separately, but would also recognize the advantage of performing the methods together.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

12/30/04